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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/701,498 11/06/2003 Enok Tjotta 372407-342961 7642

38552 7590 12/17/2004

DECHERT LLP (WASHINGTON, DC OFFICE)
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WASHINGTON, DC 20006

EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT PAPER NUMBER

1626

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	10/701,498	
Examiner	TJOTTA ET AL.	
Laura L. Stockton, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 27-38 is/are pending in the application.
- 4a) Of the above claim(s) 34-38 is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 27-33 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 10/019,229.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ____.

DETAILED ACTION

Claims 27-38 are pending in the application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 27-33, drawn to products, classified in class 548, subclass 366.4.
- II. Claims 34-38, drawn to method of use, classified in class 514, subclass 404. Note: claims 35 and 36 were included in Group II since these claims depend from claim 34 would appear that Applicants meant “A method”.

The inventions are distinct, each from the other because of the following reasons: Inventions of Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. Therefore, it would impose an undue burden on the Examiner and the Patent Office's resources to examine the instant application if unrestricted.

During a telephone conversation with John W. Ryan on

December 2, 2004, a provisional election was made with traverse to prosecute the invention of Group I, claims 27-33. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 34-38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a

product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn

process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10/019,229, filed on May 29, 2002.

Information Disclosure Statement

It is noted that an Information Disclosure Statement had not been filed at the time of this Office Action. It is suggested that if Applicants intend to file an IDS that it be filed when responding to this Office Action.

Specification

The "Brief Description of the Several Views of the Drawing(s)" heading is missing and a brief description of Figure 5 is missing (see page 12). See MPEP § 608.01(f) and 37 CFR 1.74.

Since instant independent claim 27 does not recite a carrier, diluent or excipient, claim 27 has been treated as a compound claim. Therefore, the following rejections apply.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The proviso at the end of claim 27 is confusing as to its meaning. Claim 32 and 33 do not conform to M.P.E.P. 608.01(m) since each claim must end with a period.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-31 are rejected under 35 U.S.C. 102(b) as being anticipated by:

- a) Adembri et al. {CA 54:22587h, 1960} – see CA Registry No. 114553-04-7;
- b) Franchi {CA 53:18006e, 1959} – see, for example, CA Registry No. 114159-79-4;
- c) Facchini et al. {CA 109:176423, 1988} - see CA Registry No. 37606-84-1;
- d) Eiden et al. {U.S. Pat. 3,845,213} – see Example 4 in column 4;

- e) Negrevergue {U.S. Pat. 3,833,729} – see Example 1 in column 6;
- f) Woodruff et al. {CA 82:111992, 1975} – see, for example, CA Registry No. 16860-43-8;
- g) Eiden et al. {CA 72:90407, 1970} – see, for example, CA Registry No. 25769-64-6;
- h) Giraldi et al. {CA 54:22579f, 1960} – see, for example, CA Registry No. 112441-29-9;
- i) Alexander et al. {CA 103:129, 1985} – see, for example, the compound of CA Registry No. 16860-43-8;
- j) Rahtz et al. {CA 98:100887, 1983} – see CA Registry No. 55648-39-0; or
- k) Clopath et al. {CA 94:150216, 1981} – see CA Registry No. 58648-67-2.

Each of the above cited references disclose at least one product that is embraced by the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eiden et al. {U.S. Pat. 3,845,213}, Negrevergue {U.S. Pat. 3,833,729} and Vidal et al. {WO 97/35553}, each taken alone or in combination with each other when similar utilities are asserted. Since the WO is in a non-English language, a U.S. equivalent, U.S. Pat. 6,551,360, will be referred to hereinafter.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim 1,2-diphenyl-3,5-dioxopyrazolidine compounds. Eiden et al. (column 1, lines 13-36; and especially Example 4 in column 4), Negrevergue (column 1, lines 17-55; and especially Example 1 in column 6) and Vidal et al. (formula (I) in column 1, lines 56-67; columns 2-3; and especially column 3, lines 33-36 and 58-62) each teach 1,2-

diphenyl-3,5-dioxopyrazolidine compounds that are either structurally the same as (see above 102 rejections) or structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of “some” among “many” is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., an anti-inflammatory).

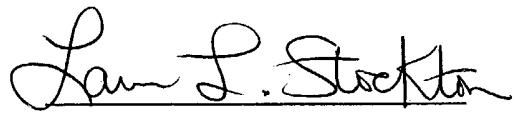
One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would

be useful in treating, for example, inflammation. Since Eiden et al. and Negrevergue each teach that 1,2-diphenyl-3,5-dioxopyrazolidine compounds are useful in treating inflammation, the combination of these prior art references would also teach the instant claimed invention. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



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Patent Examiner
Art Unit 1626, Group 1620
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December 13, 2004